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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 18

Application Number: 09/913,721
Filing Date: August 17, 2001
Appellant(s): HIRAKI ET AL.

NORMAN OBLON
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 30, 2003.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed. While applicants separately group claim 10 from claims 1-9 and 11-13, all claims stand or fall together because claim 10 in fact depend on claim 1, and applicants' argument against the rejection on claim 10 also refers to the rebuttal arguments made against the rejection on claims 1-9 and 11-13.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

Art Unit: 1617

5,260,065	MATHUR et al.	11-1993
5,013,497	YIOURNAS et al.	5-1991

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1-9 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur (US 5260065).

Mathur teaches paucilamellar lipid vesicles made of a blend of amphiphilic lipids. The reference teaches that glyceryl monostearate is among the most preferred lipids used. See col. 3, lines 41 – 51. See instant claims 12 and 13. While the reference teaches that the lipids therein are not capable of forming lamellar by itself, secondary lipids and/or cholesterol is used to form lamellar phase. See col. 3, line 65 – col. 4, line 11.

Examples 2 and 5 illustrate retinoic acid formulations wherein the retinoic acid is encapsulated within the vesicles. Example 5 employs glyceryl distearate and cholesterol. While Mathur does not show specific formulation comprising glyceryl monostearate, the reference teaches that glyceryl monostearate is nevertheless a preferred lipid in the invention.

Regarding the transitional phrase, "consisting essentially of", it is well settled in patent law that absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". See PPG Industries v. Guardian Industries, 156 F.3d 1351, 1355, 48 U.S.P.Q. 2d 1351, 1355 (Fed. Cir. 1998); MPEP § 2111.03. In this case, the

specification indicates that the present invention also contains cholesterol. Applicants bears the burden of showing the presence of oil materials other than fatty acid monoglycerides materially affect the basic and novelty of the invention. Examiner construes the term "consisting essentially of" as "comprising" in this case as there is no clear indication in specification, claims, and declaration that the presence of lipids such as cholesterol materially affects the basic and novel characteristics of the claimed invention.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the exemplified formulations in Mathur by substituting the glyceryl distearate with glyceryl monostearate as motivated by the reference, because of the expectation of successfully producing a lamellar vesicle composition with similar properties.

2. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur claims 1-9 and 11-13 above, and further in view of Yiournas et al. (US 5013497).

While Mathur is directed to paucilamellar vesicles, the reference does not teach multilamellar structures.

Yiournas generally teaches the advantages of both types of vesicles. According to the reference, while paucilamellar vesicles can transport large quantities of aqueous or lipophilic materials, their large size can preclude approach to certain tissues. See col. 1, lines 42 –68. Multilamellar vesicles are on the other hand said to be "best for encapsulation or transportation of lipophilic materials" because of the relatively large

Art Unit: 1617

amount of lipid in the lipid bilayers therein. See col. 1, lines 53 – 60. No disadvantage associated with the size of the multilamellar vesicle structure is mentioned.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the paucilamellar vesicle formulations in Mathur by formulating multilamellar vesicles as motivated by Yiournas because of the expectation of successfully producing lipid vesicles that can similarly encapsulate and transport large quantities of lipophilic materials.

(11) Response to Argument

Applicants have not shown that the instant invention is patentably distinct from the Mathur invention. While Applicants' argue that the presence of cholesterol in a lamellar vesicle composition as taught by Mathur would change the basic and novel characteristics of the claimed invention, the presently claimed lamellar structure nonetheless requires cholesterol also.

It is well settled in patent law that if an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also MPEP § 2111.03. Examiner reiterates that there must be a clear indication in the specification or claims of what the basic and novel characteristics are, and the transitional phrase "consisting essentially of" will be construed as "comprising". See PPG Industries at 1355. In this case, there is no clear indication either in the specification or claims that the basic and

Art Unit: 1617

novel characteristics of the claimed invention is using mono fatty acid monoglyceride as the only lipid in the lamellar composition. Besides the fatty acid monoglyceride, cholesterol is also used in every single example formulation in the specification. See spec. Table 6. It is also noted that monostearyl or monopalmityl glyceryl ethers are used in the compositions therein. Furthermore, applicants recite in claim 11 that the composition 'further comprises' cholesterol. While applicants assert that cholesterol is a mere additive, applicants' own disclosure indicates that cholesterol is a required element in the every formation of applicants' lamellar structure, just as Mathur uses cholesterol to form lamellar vesicles. See Mathur, col. 3, line 40 – col. 4, line 14; Examples. For these reasons, examiner takes the position that applicants have not met their burden of showing the alleged basic and novel characteristic of the claimed invention.

Applicant's argument that the reference teaches away from a composition comprising a lamellar structure having one or more fatty acid monoglyceride and one or more of vitamin A, vitamin A precursors, derivatives, and decomposed products thereof is simply erroneous. There is no teaching in the reference, either expressly or impliedly to teach away from the present invention. Applicants' remark that the Mathur composition in column 4 of the reference is not used as a carrier for a skin preparation is also incorrect and does not address the issue in this case because the prior art is also in fact directed to cosmetic formulation, and the present invention is directed a cosmetic composition. Applicants' distinction of lamellar phase verses lamellar structure is also unpersuasive because Mathur nonetheless teaches making lamellar vesicles by

Art Unit: 1617

blending a carrier containing retinoic acid into the lipophilic phase containing glyceryl distearate, cholesterol, and the dimethyl distearyl ammonium chloride, then hydrating the mixture. Thus, applicants' assertion that Mathur teaches away from the present invention is contrary to the actual teaching of the prior art.

Applicants' argument that Yiournas does not remedy the alleged deficiency of Mathur is unpersuasive because, as stated above, Mathur clearly shows that the claimed invention of claims 1-9 and 11-13 is obvious over the prior art. Yiournas was cited only to show the objective teaching that the claimed multilamellar formulation and its cosmetic benefits are well known in the art.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Gina Yu
January 26, 2004

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1/26/04